JAN 17 2013

510(k) Summary

Company:
Conventus Orthopaedics, Inc.
10200 73rd Avenue North, Suite 122
Maple Grove, MN 55369

Device Trade Name:
Conventus DRS™

Contact:
Kent R. Lind
Vice President, Quality and Regulatory
Phone: (763) 515-5000
Fax: (763) 315-4980

Prepared By:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared:
December 7, 2012

Classification:
21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class:
II

Product Codes:
HRS and HSB

Indications for Use:
The Conventus DRS™ is intended for use in the fixation of fractures of the distal radius.

Device Description:
The Conventus DRS™ is an intramedullary device intended to treat distal radius fractures. The device remains flexible during placement, but is made rigid at the completion of the surgical implant procedure. The implant is made from titanium alloy (Ti-6Al-4V) and Nitinol.

Substantial Equivalence: This 510(k) supports the substantial equivalence of the Conventus DRS™ to legally marketed devices with respect to indications for use, design, materials, and function. Specifically, this 510(k) demonstrates substantial equivalence of the Conventus DRS™ to the following predicate devices: Synthes T-Plate (Pre-amendment device), Sonoma Orthopedic Products EnsplintRx™ Intramedullary Distal Radius Fixation Device (K071809), Wright Radial Nail System (MICRONAIL®) (K040938). Like the identified predicates, the Conventus DRS™ can capture distal radius bone fragments at various angles.

Clinical evaluation, animal testing, analysis of the static and fatigue axial and bending characteristics of the device in a fracture model, biocompatibility testing, nickel release testing, and corrosion testing performed by the company demonstrate that the Conventus DRS™ is substantially equivalent to legally marketed predicate devices.

Clinical evaluation of the Conventus DRS™ was conducted outside the United States in Tier 1 countries for clinical subjects that experienced distal radius fracture due to high impact conditions (falls, sports, etc.). The clinical evaluation included collection of radiographic outcomes, functional outcomes (DASH), and adverse event information.

Radiographic success of 95% was demonstrated for study subjects 12 weeks post-operatively. The DRS™ performs substantially equivalently to the predicates at 12 weeks, 6 months, and 1 year post-operatively as assessed by DASH score. Adverse events included surgical instrument failure (4), nerve irritation and pain not requiring intervention (4), and one revision due to a fragment that was not properly secured at time of implantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

Conventus Orthopaedics, Incorporated
% Mr. Kent Lind
Vice President, Quality and Regulatory
10200 73rd Avenue North, Suite 122
Maple Grove, Minnesota 55369

Re: K102689
Trade/Device Name: Conventus DRS™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HSB
Dated: December 17, 2012
Received: December 17, 2012

Dear Mr. Lind:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin F. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102689

Device Name: Conventus DRS™

The Conventus DRS™ is intended for the fixation of distal radius fractures.

Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

2013.01.17 14:05:41 -05'00'